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A SUBJECTIVE ANALYSIS OF THE COMFORT OF TWO DIFFERENT TYPES OF SOFT CONTACT LENS MATERIALS; HIOXIFILCON B VS. HEFILCON A

BY

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Abstract:

Our research compared the comfort of two different types of soft contact lens materials; Hioxifilcon B and Hefilcon A. Both materials are considered low water content materials and are non-ionic (Group 1 materials). Hioxifilcon B is a newer material than Hefilcon A, with a water content of 49% compared to that of 45% in Hefilcon A. It has been reported to resist dehydration more than other hydrogel lenses, and therefore we hypothesized that it would be the more comfortable material. We had 13 subjects who received a lens of Hefilcon A for one eye and a lens of Hioxifilcon B for the other eye which they were to wear at the same time for two weeks. They completed a survey on the comfort of the lenses after one week of wear and then again after the second week of wear. Along with comfort, the water content of the lenses was also measured after one week of wear and again after two weeks of wear. Results showed that Hioxifilcon B did dehydrate less than Hefilcon A (dehydration of 4.11% compared to 5.95%); however there was no significant difference in the comfort of the two lenses among the subjects.

Introduction:

Hefilcon A and Hioxifilcon B are two types of material used for hydrogel soft contact lenses. All hydrogel lenses are categorized into four different groups based on their water content and whether or not the lens surface is considered to be ionic. Lenses with less than 50% water content are classified as low water content lenses. Lenses in Group 1 are low water content lenses that are non-ionic, Group 2 are high water content lenses that are non-ionic, Group 3 are low water content lenses that are ionic, and lenses in Group 4 are high water content lenses that are ionic. Ionic lenses have been shown to attract greater protein deposits than non-ionic lenses[1]. Both of the materials used in this study are categorized into Group 1, which means they are considered low water content lenses (less than 50%) and are non-ionic. The Dk (oxygen transmissibility) of hydrogel lenses are directly related to their water content, the lower the water content the lower the Dk.

Hefilcon A has been around for quite some time and is used as the material for many different contact lenses. It has a water content of 45% and a Dk of 12. It is a random copolymer of 2-hydroxyethyl methacrylate and N-vinyl pyrrolidone cross-linked with ethylene glycol dimethacrylate[2].

Hioxifilcon B is a relatively new material and is a copolymer of 2-hydroxyethyl methacrylate (2-HEMA) and 2, 3-Dihydrosypropyl Methacrylate (Glycerol Methacrylate, GMA). It has a water content of 49% and a Dk of 15. Lenses made with this material have been anecdotally reported to resist dehydration more than other hydrogel lenses with dehydration of less than 1% compared to 10% in other lenses[2].

In order to compare the hydration properties of each type of plastic, as well as to give a side-by-side analysis of perceived comfort of the two plastics, a double-blind study was completed that involved patients wearing one contact lens made of Hefilcon A (control lens) and the other made of Hioxifilcon B (study lens). Each patient was fit with the lenses and given follow-up exams after one and two weeks of wear. The patients were examined for the fit of the lenses and the eye's response to the lenses. They also completed a survey after each exam assessing the comfort of each lens. They were aware that the lenses were different from each other, but were given no other information about the lenses.

This study was completed in order to investigate the comfort of these two types of materials as well as to look at how much they dehydrated after wear. According to our research we expect that Hioxifilcon B will dehydrate less and will therefore be the more comfortable material.

Methods:

Inclusion and Exclusion criteria:

Our study population was a group of 13 optometric students. Inclusion criteria were: all participants were over the age of 18, had refractive errors of between -1.00 - -12.00 diopters

of myopia or +1.00 - +6.00 diopters of hyperopia, could have no refractive astigmatism at the spectacle plane as determined by standard refraction techniques, must be current contact lens wearers, and must be available for a baseline data gathering exam, an initial fitting exam, and two follow-up exams each separated by one week. Exclusion criteria were: participants with a history of any of the following medical conditions: collagen vascular disease, autoimmune disease, immunodeficiency diseases, ocular herpes zoster or simplex, endocrine disorders (including, but not limited to active thyroid disorders and diabetes), lupus, and rheumatoid arthritis. Subjects with a history of intraocular or corneal surgery (including cataract extraction), active ophthalmic disease or abnormality (including, but not limited to, blepharitis, recurrent corneal erosion, dry eye syndrome, neovascularization > 1mm from limbus), clinically significant lens opacity, clinical evidence of trauma (including scarring), or with evidence of glaucoma or propensity for narrow angle glaucoma in either eye, and subjects with evidence of keratoconus, corneal irregularity, or abnormal videokeratography in either eye were all specifically excluded from the study.

During the baseline data gathering exam, subjects were gauged for their appropriateness for our study by reviewing inclusion and exclusion criteria. A corneal topography was acquired and refractive error information was obtained which were used to select appropriate contact lens power and base curve. In order to allow for the most objective side-by-side comparison of the lenses, each participant received a lens of Hefilcon A for one eye and a lens of Hioxifilcon B for the other eye which they were to wear at the same time. Each of these lenses where manufactured by the same specifications, with exception to the material. This eliminated subtle differences in the lens shape from being a source of potential error.

The study was a double blinded study to eliminate examiner bias as a source of error. This required one non-blinded examiner who randomized lens types between eyes of different participants and performed the initial lens fitting. At the initial fitting, baseline information on the health of participants' ocular tissue was established with slit lamp examination using fluroscein staining. After ability to participate in the study was determined, the randomized lens was placed on the eye and left to sit for 15 minutes. After the 15 minutes were up the appropriateness of fit was determined using slit lamp examination and standard contact lens fitting protocol. One participant was removed from the study because of moderate SPK at their baseline exam. Once an appropriate fit had been established the patient was instructed to wear the lenses for a standard daily wear schedule. All participants were given a hydrogen peroxide cleaning system and were instructed to utilize the system every night upon removal of the lenses to eliminate contact lens solution variables between subjects.

After one week the participants were brought back in for a follow-up exam. This exam was conducted by one of the two "blinded" examiners. At this examination subjects would fill out surveys regarding their perceived comfort of the lenses. The areas looked at by the survey were specific symptoms experienced by the participant such as: end of the day comfort, comfortable wear time, dryness, and vision. They were also asked to rate overall comfort, initial comfort, end of day comfort, dryness, and vision as excellent, very good, good, fair, or poor. Comfortable wearing time each day was also established. Participants then numbered the comfort of each lens on a scale of one to ten with ten being completely comfortable lenses, and one being extremely uncomfortable lenses. Following the subjective

assessment, examiners reassessed the fit of the contact lenses and ocular health using a slit lamp examination. Examiners also performed refractometry on the lenses in order to assess the hydration state of each lens. At the two week follow-up this process was repeated, the lens wear was discontinued and the participants were placed back in their habitual contact lenses.

Results:

Overall Comfort:

We have summarized our results in a series of tables that will show how each patient responded on their survey regarding the comfort of the lenses. Table 1 shows the overall comfort of the lenses after 1 week and 2 weeks of wear, with A=Hefilcon A and O=Hioxifilcon B. The comfort of the lenses was rated on a scale of 10, with 10 being extremely comfortable and 1 being extremely uncomfortable. Our small population size required us to use small-value statistics, and as a result we used small population p-values to determine if there was any significance to our results. When calculating the significance of our results using small population statistics, the area falling under the distribution curve of any t score (small sample equivalent of z score) must be greater than 34.1% or 0.341 to confirm our original hypothesis (denote a significant effect from the lenses on comfort and hydration). In all comfort criteria our sample scores (Hioxifilcon B) were less than the control scores (Hefilcon A) meaning that no beneficial effect of Hioxifilcon B over Hefilcon A, in regards to perceived comfort, was noted.

Table 1: Overall Comfort

	Week 1	Week 2	Average
Mean Comfort A	4.9	4.6	4.75
Mean Comfort O	4.67	4.39	4.53
Standard Deviation A	2.618	2.269	2.401
Standard Deviation O	2.39	2.89	2.786
Mean change in A comfort	X	X	-0.3
Mean change in O comfort	X	X	-0.28
Standard Deviation of change in A	X	X	1.731
Standard Deviation of change in O	X	X	1.2
T-Value	-0.3334	-0.2517	-0.2735

The comfort means of Hefilcon A were higher than the comfort means of Hioxifilcon B on both weekly surveys. These results reject our original hypothesis that Hioxifilcon B will be more comfortable because it dehydrates less on the eye.

Comfort Expanded:
Knowing that comfort is often assessed differently from person to person, we broke down how the lenses felt into separate components. This was an attempt to bring to light any differences between the plastics that may have gone unnoticed under the more generic assessment of "comfort". We asked the subjects to assess the lenses by these categories: "End of Day Comfort", "Vision", "Dryness", and "Comfortable Wear Time". They were asked to designate each lens as "excellent", "very good", "good", "fair", and "poor" based on how it performed under each category. It was noticed immediately upon comparing data between lenses that the two plastics were regarded as remarkably similar in the population's assessments of them, often times with the ratings of excellent, very good, good, fair, and poor varying only by one or two subjects between lenses. This was noted across the board on all areas of subjective assessment. In order to objectively analyze these subjective response, we assigned a number value of 1-5 to these ratings, with excellent as 5 and poor as 1. This allowed us to quantify the responses, which in turn allowed further analysis. Tables 2-5 summarize the results of the survey.

In Table 2, the average overall end of day comfort of Hefilcon A and Hioxifilcon B was rated between fair and poor. In Table 3, the average overall dryness of Hefilcon A and Hioxifilcon B was rated between good and fair. In Table 4, the average overall vision of Hefilcon A and Hioxifilcon B was rated between very good and good. In Table 5, the average overall comfortable wear time of Hefilcon A was rated between good and fair, and Hioxifilcon B was rated between fair and poor.

Table 2: End of Day Comfort

	Week 1	Week 2	Average
Average A	1.75	2	1.875
Average O	1.75	1.9167	1.8333
Standard Deviation A	0.9653	1.1281	1.0347
Standard Deviation O	1.1381	1.3789	1.2394
T-Value	0	-0.2093	-0.1647

Table 3: Dryness

	Week 1	Week 2	Average
Average A	2.1667	2.5833	2.375
Average O	2.0833	2.500	2.2917
Standard Deviation A	1.1146	1.3231	1.279
Standard Deviation O	1.3231	1.2992	1.3345
T-Value	-0.2479	-0.2221	-0.0306

intervals (5% level of confidence), and small sample p scores that Hioxifilcon did dehydrate significantly less, with a t score of 1.984 giving a б (significance level) of 47.61 %, so б > P. This indicates our hypothesis of comparatively less dehydration from Hioxifilcon B to Hefilcon A was supported. Alternately, when treating the lenses as independent variables, we were able to indicate that for a population size 22 (total scores from two weeks, note: each group had an n of 22 over two weeks) with a predicted total standard deviation of 2.49, a critical z score of greater than or equal to 1.80 was needed at 5% significance to suggest a true difference in the rates of dehydration between the lenses. The difference between the two groups' means fell past that mark at 1.84 allowing us to conclude that there was a significant difference between the means of dehydration.

Discussion:

As outlined above, Hioxifilcon B resisted dehydration significantly better than Hefilcon A, with Hioxifilcon B losing only 4.11 % water content compared to Hefilcon A's average loss of 5.95 % (T-score of 1.9837), However, while objectively this data indicates that Hioxifilcon B maintains a more stable hydration profile than Hefilcon A, the effect on a patient's perceived comfort while wearing the lenses was negligible between the two, as indicated by analysis of subjective data. According to the subjects' input, both lenses performed similarly in all respects, and no statistically significant perceived difference was noted between the plastics. Our study suggests that Hioxifilcon B, while resisting dehydration more effectively than Hefilcon A, delivers no perceived increase in comfort while wearing the lenses.

There are potential problems with our study which limit its ability in aiding to make a definite clinical comment on differences between the plastics. Our sample of 12 participants was admittedly small, and a larger sample size would be needed to increase the study's reliability. Subjective responses are very difficult to standardize – the same sensation may be described as very uncomfortable by one person, but may be noted as no more than a slight irritation by another. We were, at least, able to eliminate intra-subject variability through each person wearing the lenses at the same time, and all lenses undergoing identical manufacturing processes. Unfortunately, given the nature of the study we were unable to eliminate inter-subject variability. This may have caused the data to be unrealistically distributed, and, again, due to the small population size may have affected the study's reliability. Also, due to the fact that our populations' schedules varied dramatically we were unable to standardize a time to perform follow-ups. This led to average wear time of the lenses varying by as much as 5 hours on follow-up days, which introduced another variable into our hydration measurements. Finally, while no differences were noted in ocular health between eyes at follow-ups, it is possible, given the hydration differences between the lenses, that with long term use Hioxifilcon B would create slightly less drying and hypoxia of the cornea, and result in less complaints of ocular discomfort compared to Hefilcon A. This is only speculation, but demonstrates that differences may have been masked by the limited time the study took place within.

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